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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number	09/614,790
Filing Date	July 12, 2000
First Named Inventor	Sharon F. Kleyne
Art Unit	1617
Examiner Name	Wang, Shengjun
Total Number of Pages in This Submission	20
Attorney Docket Number	HME/7982.001

ENCLOSURES (Check all that apply)		
<input checked="" type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/ Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation <input type="checkbox"/> Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to TC <input checked="" type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input type="checkbox"/> Other Enclosure(s) (please identify below):
Remarks		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Howard Eisenberg, Esq.		
Signature			
Printed name	Howard Eisenberg		
Date	April 3, 2008	Reg. No.	36,789

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Signature			
Typed or printed name	Howard Eisenberg	Date	April 3, 2008

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Effective on 12/08/2004.

Fees listed are for the Consolidated Appropriations Act, 2005 (H.R. 4818).

FEE TRANSMITTAL For FY 2008

Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT

(\$)
0**Complete if Known**

Application Number	09/614,790
Filing Date	July 12, 2000
First Named Inventor	Sharon F. Kleyne
Examiner Name	Wang, Shengjun
Art Unit	1617
Attorney Docket No.	HME/7982.001

METHOD OF PAYMENT (check all that apply)

Check Credit Card Money Order None Other (please identify): _____
 Deposit Account Deposit Account Number: 50-1773 Deposit Account Name: Howard Eisenberg

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

Charge fee(s) indicated below Charge fee(s) indicated below, except for the filing fee
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FEE CALCULATION**1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

<u>Application Type</u>	<u>FILING FEES</u>		<u>SEARCH FEES</u>		<u>EXAMINATION FEES</u>		<u>Fees Paid (\$)</u>
	<u>Fee (\$)</u>	<u>Small Entity Fee (\$)</u>	<u>Fee (\$)</u>	<u>Small Entity Fee (\$)</u>	<u>Fee (\$)</u>	<u>Small Entity Fee (\$)</u>	
Utility	310	155	510	255	210	105	_____
Design	210	105	100	50	130	65	_____
Plant	210	105	310	155	160	80	_____
Reissue	310	155	510	255	620	310	_____
Provisional	210	105	0	0	0	0	_____

2. EXCESS CLAIM FEESFee Description

Each claim over 20 (including Reissues)

Each independent claim over 3 (including Reissues)

Multiple dependent claims

<u>Total Claims</u>	<u>Extra Claims</u>	<u>Fee (\$)</u>	<u>Fee Paid (\$)</u>	<u>Small Entity</u>	
				<u>Fee (\$)</u>	<u>Fee (\$)</u>
9	- 20 or HP = 0	x 25	= 0	50	25

HP = highest number of total claims paid for, if greater than 20.

<u>Indep. Claims</u>	<u>Extra Claims</u>	<u>Fee (\$)</u>	<u>Fee Paid (\$)</u>	<u>Multiple Dependent Claims</u>	
				<u>Fee (\$)</u>	<u>Fee Paid (\$)</u>
1	- 3 or HP = 0	x 105	= 0	370	185

HP = highest number of independent claims paid for, if greater than 3.

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$260 (\$130 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

<u>Total Sheets</u>	<u>Extra Sheets</u>	<u>Number of each additional 50 or fraction thereof</u>	<u>Fee (\$)</u>	<u>Fee Paid (\$)</u>
_____	- 100 = _____	/ 50 = _____ (round up to a whole number)	x _____	= _____

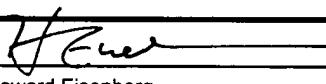
4. OTHER FEE(S)

Non-English Specification, \$130 fee (no small entity discount)

Other (e.g., late filing surcharge): _____

Fees Paid (\$)

SUBMITTED BY

Signature		Registration No. (Attorney/Agent) 36,789	Telephone (484) 412-8419
Name (Print/Type)	Howard Eisenberg		

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
PATENT APPLICATION EXAMINING OPERATIONS**

In re the Application of :
Sharon F. Kleyne : Group Art Unit: 1617

Serial No. 09/614,790 : Examiner: Shengjun Wang

Filed: July 12, 2000 : Tel. No. (571) 272-0632

For a Patent for : Date: April 3, 2008
METHOD AND KIT FOR MOISTURIZING
THE SURFACE OF THE EYE

**REQUEST FOR REHEARING OF DECISION BY THE BOARD
UNDER 37 C.F.R., §41.50(b) and §41.52**

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir,

In response to the Decision on Appeal mailed on February 26, 2008, Appellant submits this Request for Rehearing, in accordance with 37 C.F.R., §41.50(b) and §41.52. The Decision contained a new ground of rejection. Accordingly, as stated in 37 C.F.R. §41.52(a)(3), new arguments are permitted to be made in this Request for Rehearing.

REMARKS

I. Rejection for anticipation under 35 U.S.C. §102(b)

The Board has rejected claims 90-93 and 97-101 under 35 U.S.C. §102(b) as being anticipated by the disclosure of Junkel, U.S. Patent No. 5,620,633. Appellant requests rehearing of this basis of rejection for the reasons following.

A. Basis of rejection by the Board

In formulating this basis of rejection, the Board stated that Junkel discloses a portable misting device for atomizing a liquid mist, such as water, which may be used by sunbathers and athletes as a cooling device. The Board states that, "As is customary such devices are used to fan and cool the body, including the face." The Board further notes that the mist is sprayed from a sealed container.

In the Decision, the Board states that the record contains no evidence that a person of ordinary skill in the art would not use the misting device of Junkel to administer a mist to the face, including the eyes for a period of time within 10 seconds. The Board cites *In re Best*, 562 F.2d 1252, 1255, 195 U.S.P.Q. 430, 433 (C.C.P.A. 1977) for its description of the burden of a patent applicant pertaining to a rejection based on inherency. In particular, the Board states that:

Appellant has the burden of proving that the method and mist provided by the device of Junkel produces a droplet size different from that claimed and that the mist droplets of Junkel will wash away the tear film as opposed to hydrating the aqueous layer of the eye.

In the Decision, the Board states that the record contains no evidence that a person of ordinary skill in the art using the misting device of Junkel would not inherently administer a mist

to the face, including the eyes for a period of time within 10 seconds. The Board again cites *In re Best* and states that:

it remains the burden of Appellant under the principles set forth in *In re Best* to show that the misting device of Junkel necessarily provides an amount of fluid which would flood the eye.

B. Basis for Appellant's request for rehearing

Appellant respectfully submits that the Board has incorrectly stated and applied the law pertaining to rejections based upon inherency and that, with a proper application of the law of inherency, it is clear that the claims are not anticipated by the disclosure of Junkel.

The law of inherency has been clarified on numerous occasions by the Court of Appeals for the Federal Circuit. As stated in *In re Robertson*, 49, U.S.P.Q.2d 1949, 1950-1951 (Fed. Cir. 1999):

If the prior art reference does not expressly set forth a particular element of the claim, that reference still may anticipate if that element is "inherent" in its disclosure. To establish inherency, the extrinsic evidence "must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill in the art." Inherency, however, may not be established by probabilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.

The court in *Electro Medical Systems SA v. Cooper Life Sciences Inc.*, 32 U.S.P.Q.2d 1017, 1020 (Fed. Cir. 1994), held as follows regarding inherency:

We do not agree that the subject matter of the claims was anticipated. The mere fact that a certain thing may result from a given set of circumstances is insufficient to prove anticipation. EMS was required to prove that an unpressurized flow is necessarily present in the Ruemelin disclosure, and that it would be so recognized by persons of ordinary skill.

The U.S. Patent Office Board of Patent Appeals and Interferences has also discussed the law pertaining to inherency. In *Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Int. 1990), the Board stated that:

In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic *necessarily* flows from the teachings of the applied prior art. (emphasis in the original).

Thus, it is clear from case law in the Federal Circuit Court of Appeals and in the Board of Patent Appeals & Interferences, that, in order for a limitation to be disclosed under the doctrine of inherency, the limitation must *necessarily* flow from the disclosure and that one skilled in the art would recognize this necessary result.

Appellant respectfully submits that the Board has erred in requiring Appellant to provide a showing (1) that the device of Junkel produces a droplet size different from that claimed and that the mist droplets of Junkel will wash away the tear film as opposed to hydrating the aqueous layer, and (2) that the misting device of Junkel necessarily provides an amount of fluid that will flood the eye.

As clearly held in numerous cases before the Federal Circuit Court of Appeals and the Board of Patent Appeals and Interferences, the correct burden on a patent applicant regarding a purportedly inherent disclosure in a prior art reference is that the patent applicant has to show that the claimed limitation is not a necessary result of the prior art disclosure or that one skilled in the art would not recognize this necessary result. This is in marked contrast and is diametrically opposed to the burden placed upon Appellant by the Board in the present Decision.

The present record clearly provides a showing that the misting device of Junkel may be directed towards parts of the body other than the eyes. Junkel discloses that the misting device provides an air-cooled mist spray that is delivered to a user. See column 2, lines 3-7. The device is useful for sunbathers and those engaged in athletic pursuits. See column 8, lines 19-23.

Appellant submits that it is clear from the disclosure of Junkel that the mist from the device may be directed towards parts of the body other than the face, and particularly other than the eyes. For example, sunbathers and athletes may direct the mist from the device of Junkel to the chest, the back, the arms, or the legs. It is submitted, therefore, that the mist of Junkel is not necessarily directed towards the eyes. Perhaps it is true that a sunbather or athlete may direct the mist from the device of Junkel to the eyes. However, whether or not this is so, it is clear that the direction of the mist from the device of Junkel does not necessarily flow from the disclosure of Junkel.

In accordance with the doctrine of inherency as applied in the *In re Robertson, Electro Medical Systems SA v. Cooper Life Sciences Inc.*, and *Ex parte Levy* cases, Appellant respectfully submits that the Board is incorrect in its present application of the doctrine of inherency regarding the application of the mist of Junkel to the face, and particularly to the eyes.

Secondly, Junkel does not disclose an amount of fluid that is directed towards the body of a user. The amount of fluid that is sufficient to flood the eye is extremely small, less than 10 microliters. A single drop of fluid from a drop application bottle is at least twice this size, 20 to 30 microliters. Therefore, in order for a mist from the misting device of Junkel that is directed towards the eyes of a user not to flood the tear film, the amount reaching the eye would have to be an amount less than that which is contained in half of one standard drop.

The pertinent question pertaining to the present situation is whether the amount of water administered by the device of Junkel would necessarily be less than that which is contained in one standard drop. Appellant submits that the device of Junkel may be used to apply amounts of fluid well in excess of this amount and, therefore, that the amount of fluid less than that which will flood the eye is not inherent in the disclosure of Junkel.

An illustrative and similar situation to the present case was discussed in *Transclean Corp. v. Bridgewood Services Inc.*, 62 U.S.P.Q.2d 1865, 1871 (Fed. Cir. 2002). In that case, the court discussed whether or not the claims of a patent were invalid for anticipation based upon the inherency of disclosure of a prior art reference. In holding that the prior art reference did not inherently disclose the invention, the court stated as follows:

Thus, the Japanese patent explicitly discloses that fluid weight is equalized, not necessarily fluid flow rate. Although it is possible that the detection means could under some circumstances (e.g., if the response time for the feedback loop is sufficiently fast) effectively equalize the flow rates as well, it is also possible for that not to be the case. Because anticipation by inherent disclosure is appropriate only when the reference discloses prior art that must *necessarily* include the unstated limitation, the Japanese patent cannot inherently anticipate the claims of the '080 patent. We conclude, as did the district court, that Bridgewood did not raise any genuine issue of material fact regarding anticipation of claim 1 by the Japanese patent, and we therefore affirm the court's conclusion that Transclean is entitled to summary judgment of non-anticipation as to the Japanese patent. Thus, we affirm the court's conclusion that the claims of the '080 patent are not invalid under 35 U.S.C. § 102 as being anticipated by the Becnel or Japanese prior art patents. (citations omitted, italics in original)

In summary, Appellant respectfully submits that the Board has applied an erroneous standard for determining whether elements missing in a prior art reference are inherent in that disclosure. It is submitted that Appellant does not bear the burden of showing that the disclosure

of the prior art reference is necessarily outside the scope of the present claims. Rather, the burden on Appellant is to show that the features of the claims do not necessarily flow from the disclosure of the prior art. Appellant respectfully submits that this burden has been met.

C. Conclusion

Appellant submits that the presently claimed invention is not disclosed or suggested by the disclosure of Junkel and, as discussed above, features called for in the present claims are not inherent in the disclosure of Junkel. Accordingly, Appellant respectfully requests a rehearing pertaining to the issue of the rejection of claims 90-93 and 97-101 as being anticipated under 35 U.S.C. §102(a) by the disclosure of Junkel, U.S. Patent No. 5,620,633, and further requests the Board to withdraw the rejection of the claims on this ground.

II. Rejection for obviousness under 35 U.S.C. §103(a)

The Board has rejected claims 90-93 and 97-101 under 35 U.S.C. §103(a) as being obvious in view of the disclosure of Embleton, WO 97/23177, in view of the disclosures of Hahn, U.S. Patent No. 5,893,515, and Hutson, U.S. Patent No. 5,588,564. Appellant requests rehearing of this basis of rejection for the reasons following.

A. Basis of rejection by the Board

The Board cites Embleton for its disclosure of a device for delivering an ophthalmic treatment fluid to the eye, which fluid is administered by the device in the form of a jet or stream

in a volume of 10 microliters or less, preferably 3 to 8 microliters. The Board states that Embleton discloses that one of the treatment fluids that may be administered is water.¹

The Board cites Hutson for its disclosure of administration of an ophthalmic liquid in the form of a mist to the eye. The Board likewise cites Hahn for its disclosure of administration of an ophthalmic liquid to the eye.

The Board found that it would be obvious to replace the jet or stream of Embleton with the mist of Hutson or Hahn to administer an amount of water between 3 to 8 microliters to the surface of the eye. In formulating this rejection, the Board cited the recent Supreme Court decision of *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 82 U.S.P.Q.2d 1385 (2007) for its holdings that (a) in making an obviousness determination over a combination of prior art references, it is important to identify a reason why persons of ordinary skill in the art would have attempted to make the claimed subject matter, (b) if a technique has been used to improve one device, and a person of ordinary skill would recognize that it would be used in similar devices in the same way, using the technique is obvious unless its application is beyond that person's skill, and (c) when the question is whether a patent claiming the combination of elements or prior art is obvious, the relevant question is whether the improvement is more than the predictable use of prior art elements according to their established functions.

¹ The statement by the Board that Embleton discloses the administration of a treatment fluid that is water is erroneous, as evidenced in testimony in a Declaration by Dr. Rachael Garrett.

B. Basis for Appellant's request for rehearing

1. *KSR Int'l Co. v. Teleflex Inc.*

Because the Board cited the *KSR Int'l* case, this case and its pertinence to the present case is discussed.

KSR Int'l involved the issue of whether a factfinder, such as a court or the Patent Office, can combine prior art references that, when taken together, disclose or suggest an invention when there is no specific teaching, suggestion, or motivation in the prior art to combine the teaching of the references. In this case, the Supreme Court held that the teaching/suggestion/motivation (TSM) test used to determine the propriety of combining prior art references should not be applied in a rigid, formalistic manner, but rather a factfinder must take account of the inferences and creative steps that a person of ordinary skill in the art would employ.

In particular, the Supreme Court stated that a factfinder is not limited to consider only art that deals with the specific problem that a patentee or applicant is attempting to solve and is not limited to consider only elements of prior art that are designed to solve the same problem that the patentee or applicant is attempting to solve. 127 S. Ct. at 1742, 82 U.S.P.Q.2d at 1397. The Supreme Court further warned courts and patent examiners against using hindsight when determining whether an invention is patentable, but stated that rigid rules that deny factfinders recourse to common sense should not be utilized.

The issue in *KSR Int'l* dealt with the issue of the placement of an electronic sensor in a pedal used in an automobile. The Court found that the prior art taught all of the features of the claimed invention and that the features were used in the invention at issue in a similar way and that the changes in the invention at issue were not more than the predictable use of prior art

elements according to their established functions. Therefore, the invention was found to be obvious in view of the prior art.

2. The prior art

The present case differs significantly from the type of case addressed by the Supreme Court in *KSR Int'l*. In *KSR Int'l*, the invention was a mechanical invention in which all elements were used according to their established functions and in a similar way to that of the present art. That is not so in the present case.

The present invention is based on the discovery by Appellant that moisturization of the eye is best achieved by using a very small amount of fluid and that water itself is the best fluid to use for this purpose. Each of these features is in opposition to the state of the art in the field of moisturizing the eye. As called for in the present claims, an aqueous fluid consisting essentially of water is administered to the surface of the eye in an amount that is less than that which will wash away the tear film. The claims further call for administration of the water in the form of a mist.

The prior art belongs to two separate fields within ophthalmology. One field is that of topical administration of treatment substances, such as a medication in the form of a liquid, to the surface of the eye. The second field is that of moisturizing the surface of the eye. These two fields present different problems that are addressed in different manners, and what works in one field does not necessarily work in the other field.

The primary reference, Embleton, as stated in Embleton itself, concerns the field of ophthalmic treatment by administering a treatment substance in the form of a liquid to the surface of the eye.

When topically administering a liquid treatment substance to the eye, it is important to provide an amount of liquid that is no greater than that which will be retained by the eye. One reason for this is that, if an amount of liquid that is greater than that which can be retained by the eye is administered, the excess will run out of the eye resulting in wastage of the medicament. Another more serious reason is that, if liquid runs out of the eye, one cannot know how much of the administered medication actually was retained by the eye and, consequently, there would be a lack of precision in dosing. A third and a much more serious reason is that, when liquid runs out of the eye, a portion of the lost liquid drains into the tear duct and into the nasal passages. A person would then typically inhale this liquid, which would cause the medication in the liquid to enter the systemic circulation of the person.

For these reasons, and others, when administering treatment fluids to the eye, it is well known in the art to administer a very small amount of the treatment fluid. Embleton discloses a device that can be used to deliver amounts between 3 and 10 microliters to the eye.

In addition, when topically administering a treatment fluid to the eye, it is important to make sure that the treatment fluid actually gets into the eye. If treatment fluid is administered to the face and not to the eye itself, the portion of the treatment fluid that misses the eye is wasted and there is also a lack of precision in determining how much treatment fluid actually got into the eye.

For these reasons, it is well known to administer treatment fluids to the eye in the form of a jet or stream that can target the eye itself. The device of Embleton delivers the treatment fluid in the form of a jet or stream.

The secondary references, Hahn and Hutson, concerns the field of moisturizing the surface of the eye.

In this field, unlike the field of topical administration of a treatment fluid to the eye, it is not essential to target a moisturizing liquid to a portion of the eye. Moreover, if a portion of the moisturizing liquid misses the eye and is administered to portions of the face other than the eye, this is not generally a problem.

Consequently, Hahn and Hutson disclose the administration of a moisturizing liquid to the eye in the form of a mist.

In the field of moisturizing the eye, because the goal is to ensure that the eye is moisturized, an amount of fluid that floods the eye is generally administered. These large amounts of fluid may be used in this field, although they cannot be used in the field of administering a treatment fluid to the eye, because the moisturizing fluids have to be administered in an amount that will surely moisturize the eye, the moisturizing fluid does not have to be precisely dosed, and the moisturizing fluid is not biochemically active and so will not cause toxic deleterious effects if it enters the systemic circulation. Hahn discloses that a drop is administered, sufficient to saturate the eye. This quantity of fluid is about 5 to 10 times the amount of fluid that makes up the aqueous layer of the tear film. Hutson is silent as to the quantity of moisturizing fluid that is administered.

In the field of moisturizing the eye, the accepted dogma is that an administered moisturizing fluid must have sufficient osmolarity to avoid causing an osmotic shock to the

surface of the eye.² Consequently, all eye moisturizing fluids, prior to that of the present invention, whether based on water, saline, or oil, contain additional dissolved solutes so that the fluid has an osmolarity that is near that of the tear film. These fluids may be isotonic, that is having an osmolarity about that of the tear film, about 310 mOsm, or may be hypotonic, having an osmolarity that is slightly below that of the tear film, for example about 280 mOsm. Hahn and Hutson disclose that various fluids and solutions are used to moisturize the eye. Neither of these references discloses the administration of water itself to moisturize the eye.

3. The present invention

The present invention is based on the discovery that moisturization of the eye is optimally obtained when only small amounts of liquid are administered and on the further discovery that moisturization is optimal when it is water with a very low level of solutes that is administered in these small amounts. Both of these discoveries are in direct contrast to long accepted dogma in the field of eye moisturization.

Although it has long been known, as disclosed in Embleton, that small amounts of liquid, such as about 3-10 microliters, are preferred when administering a treatment fluid to the eye, prior to the present invention such amounts of liquid have never been disclosed for administering fluid for the purpose of moisturizing the eye and not for administering a treatment to the eye.

Further, prior to the present invention, liquid water itself, without additional solutes, has never been disclosed to be useful as a moisturizing fluid for the eyes. In fact, it is an established

² Osmotic shock is a sudden change in the solute concentration around a cell, causing a rapid change in the movement of water across its cell membrane.

dogma in ophthalmology that water by itself cannot be topically administered to the eye because it causes a stinging sensation and osmotic shock.³

It is respectfully submitted that the invention is novel and non-obviousness based on the inclusion of these two features in the claims.

Additionally, the present claims call for administration of this amount of water in the form of a mist. It is respectfully submitted that this is a further distinction over the disclosure of Embleton, but that this feature is not necessary to distinguish over Embleton because neither Embleton nor the other prior art discloses the use of water⁴ for moisturizing the eye and Embleton is concerned with a field that, in many ways, is diametrically opposite that of the field of moisturizing the eye.

4. The prior art in view of *KSR Int'l*

In accordance with *KSR Int'l*, prior art may be considered and combined even if the prior art does not deal with the specific problem that an applicant is attempting to solve and elements of the prior art that address different problems that an applicant is attempting to solve may be considered. However, the Supreme Court cautioned that, even though rigid rules should not be utilized when determining obviousness in view of a combination of prior art references, the use of hindsight must be avoided.

³ Appellant has previously provided a Declaration of Dr. Philip Paden who testified that it is a long accepted doctrine in ophthalmology that water by itself cannot be administered to the eye because it causes stinging and osmotic shock.

⁴ Appellant has previously submitted a Declaration of Dr. Rachael Garrett in which she testifies that one skilled in the art would understand the disclosure of Embleton to pertain to fluids based upon water, saline, or oils, rather than the administration of pure water, pure saline, or pure oil to the eye.

Embleton discloses a device for administering a jet or stream of a treatment fluid to the eye, which treatment fluid may be water, saline, or oil-based, and which treatment fluid is administered in an amount between 3 and 10 microliters. Hutson and Hahn disclose administering a mist of a moisturizing fluid to the eye in an unspecified amount (Hutson) or in an amount that saturates the eye, about one drop (Hahn).

Applicant submits that the combination of Embleton, Hutson, and Hahn does not suggest the present invention. None of the cited references discloses the use of a fluid consisting essentially of water, as is called for in the claims. Appellant has previously provided Declarations of Drs. Rachael Garrett and Philip Paden who testified, respectively, that Embleton would not be understood by one of skill in the art to disclose an eye moisturizing fluid consisting essentially of water and that the use of water as a moisturizing fluid is contrary to accepted dogma in the field of ophthalmology.

For this reason alone, Appellant submits that the claims are not obvious over the prior art.

Additionally, Appellant respectfully submits that it is improper to combine the disclosure of a mist in Hutson and Hahn, which pertain to moisturizing the eye, with the disclosure of Embleton, which deals with administering a treatment fluid, because this would render the device of Embleton inoperative for its stated purpose. As disclosed in several places in Embleton, including the Abstract, the device of Embleton produces a jet or stream which permits the device to serve its purpose of targeting a medication to a particular site in the eye. If the device of Embleton produced a mist of fluid, it would no longer serve its purpose of administering a treatment fluid to the eye and would in no way be able to target a medication to the eye or to a particular site in the eye.

Additionally, Appellant respectfully submits that one skilled in the art would not combine Embleton's disclosure of an amount of treatment fluid less than 10 microliters with the disclosure of either Hahn or Hutson and so arrive at a method for moisturizing the eye by administering such a small volume of fluid. It is well understood by those skilled in the art of ophthalmology that the topical administration of treatment fluids to the eye and the administration of moisturizing fluids to the eye are very different, as discussed above. It is noted that the benefits of small fluid volumes for administering treatment fluids has been known for quite a long time. It is specifically noted that Embleton discloses, in the bridging sentence of pages 1 and 2, that the benefits of providing a high concentration of drug in a small volume was reported as early as 1978. However, in the 30 years since that time, to Appellant's knowledge, there have been no publications except for the present application that disclose the use of such small volumes of fluid for moisturizing the eye.

Accordingly, Appellant submits that it is only through the impermissible use of hindsight that the Board has combined the Embleton, Hahn, and Hutson references to find the present invention obvious. Appellant discovered that small amounts of fluid produce optimal moisturization of the surface of the eye. This was unknown before the present application. Applicant discovered that, by replacing water lost in the aqueous layer of the tear film of the eye by the administration of water, optimal moisturization of the surface of the eye could be obtained. This was not known prior to the present application.

It is only with knowledge of the disclosure of the present application that one would combine the Embleton, Hahn, and Hutson references in the way that the Board has in order to find that the present invention is obvious. It is submitted that, without the knowledge obtained

from the present specification, one skilled in the art would not combine these references as the Board has. Such use of the knowledge available only through the present invention constitutes impermissible hindsight. The Supreme Court, in *KSR Int'l*, warned against the use of hindsight in formulating rejections for obviousness. There are also a great many Federal Circuit opinions that caution against the use of hindsight in determining obviousness.

C. Conclusion

Appellant submits that the presently claimed invention is not disclosed or suggested by the combined disclosures of Embleton, Hahn, and Hutson and that the present rejection of the claims based on the combination of these references utilizes impermissible hindsight. Accordingly, Appellant respectfully requests a rehearing pertaining to the issue of the rejection of claims 90-93 and 97-101 as being obvious under 35 U.S.C. §103(b) in view of the combined disclosures of Embleton, WO 97/23177, in view of the disclosures of Hahn, U.S. Patent No. 5,893,515, and Hutson, U.S. Patent No. 5,588,564, and further requests the Board to withdraw the rejection of the claims on this ground.

Conclusion

For the above reasons and for those provided in the Appeal Brief, the Board is respectfully requested to grant Appellant's request for a rehearing of the previous Decision of the Board and to withdraw the new bases of rejection of the claims contained in the Decision of the Board.

Respectfully submitted,

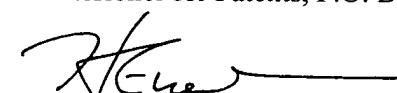


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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on April 3, 2008.

Dated: 4/3/2008



Howard M. Eisenberg